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PATENT

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Applicant: Paboojian et al. Applicant's Ref: 0050.01

Application No: 09/731,318

Filed: December 6, 2000

Title: RECEPTACLES TO FACILITATE
THE EXTRACTION OF POWDERS

Examiner: Mendoza, Michael G. Group Art Unit: 3731

APPEAL BRIEF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Final Rejection of August 19, 2005, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

(1) Real Party in Interest

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 150 Industrial Road; San Carlos, California 94707.

(2) Related Appeals and Interferences

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) Status of Claims

Claims 1-4, 13-22, and 31-34 are presently pending in the case. Claims 1-4 have been finally rejected. Claims 13-22 and 31-34 have been allowed. The rejection of each of claims 1-4 is hereby appealed.

(4) Status of Amendments

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

(5) Summary of the Invention

A receptacle (e.g. element 10) for holding fine powder medicament is disclosed. The receptacle comprises a receptacle body (12) that defines an enclosed cavity (20), wherein the receptacle body has a top end (14) and a bottom end (16). A version of the receptacle can be seen in Figures 1 and 2. The bottom end (16) of the receptacle body (12) includes a raised central region (26) that extends upwardly into the cavity (20).

The raised central portion (26) of the receptacle body (12) allows the fine powder medicament to be acrosolized and delivered out of an opening that has been created in the enclosed receptacle or through an extraction tube that has been inserted into the enclosed receptacle (10) as shown in Figures 3 and 4. Initially, however, the cavity is enclosed with the fine powder medicament stored within the enclosed cavity.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant requests review of the Examiner's following grounds of rejection:

Claims 1-4 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 3,980,074 to Watt et al (hereinafter Watt et al).

(7) Argument

Appellant believes each of claims 1-4 are improperly rejected and are therefore allowable for the following reasons.

The rejection of independent claim 1 under 35 U.S.C. 102(b) is improper

Watt et al does not anticipate claim 1. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Claim 1 is to a receptacle comprising, inter alia, a receptacle body that defines an <u>enclosed</u> cavity containing powdered medicament. Watt et al does not disclose an <u>enclosed</u> cavity. Instead, the cavity of Wall et al has several openings, such as vents 11 and opening 2. Since all features of claim 1 are not disclosed by Watt et al, the reference does not anticipate the claim and Applicant requests reversal of the rejection.

The cavity of Watt et al is not "enclosed." As discussed throughout Appellant's specification, the powder medicament is contained within an enclosed cavity, such as a sealed blister pack (see page 7, lines 25-35). In this way, the powder medicament may be stored on the shelf prior to use and may be protected from the environments degrading effects. The enclosed cavity is then punctured or otherwise opened to allow for the powder medicament to be aerosolized. In an alternative version, openings may be preformed into the enclosed cavity and these preformed openings include a removeable cover that allows for access to the cavity (see page 9, lines 28-34). Watt et al's cavity is, thus, not in any way "enclosed."

Claims 2-4 depend from claim1 and are allowable over Watt et al for at least the same reasons as their base claim.

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

NEKTAR THERAPEUTICS (formerly INHALE THERAPEUTIC SYSTEMS)

Dated: 145EP 2006

Gry V. Tucker Reg. No. 45,302

Please send all correspondence to:
Guy Tucker
Nektar Therapeutics
(formerly Inhale Therapeutic Systems, Inc.)
150 Industrial Road
San Carlos, CA 94070

Phone: (650) 620-5501 Fax: (650) 620-6395

(8) Claims Appendix

1. A receptacle comprising:

a receptacle body that defines an enclosed cavity containing powdered medicament, wherein the receptacle body has a top end and a bottom end, and wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity.

- 2. A receptacle as in claim 1, wherein the receptacle body further comprises at least one curved wall that in combination with the raised central region forms a generally semitoroidal geometry in the cavity.
- 3. A receptacle as in claim 1, wherein a portion of the bottom end is flat in geometry.
- 4. A receptacle as in claim 1, wherein the receptacle body further includes a tab extending from the cavity.
- 13. A method for aerosolizing a powdered medicament, the method comprising:

providing a receptacle comprising a receptacle body that defines an enclosed cavity, wherein the receptacle body has a top end and a bottom end, and wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity;

inserting a bottom end of an extraction tube into the cavity such that the bottom end of the extraction tube is aligned with the raised central region and is spaced above the bottom end of the receptacle;

forming vents in the top end of the receptacle about a periphery of the cavity; and

flowing a gas stream through a least a portion of the extraction tube to draw air through the vents and then through the cavity to move the powder in the cavity into the extraction tube where the powder is entrained in the gas stream to form an aerosol.

14. A method as in claim 13, wherein the receptacle includes a curved wall, and wherein the air flows along the wall to remove substantially all powder from the receptacle.

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- 15. A method as in claim 13, wherein the air drawn by the gas stream flows through a flow area, and further comprising reducing the flow area as the air flows through the receptacle and the extraction tube to accelerate the flow of air through the receptacle.
- 16. A method as in claim 15, wherein the vents form a first flow area, wherein a gap between the extraction tube and the bottom end of the receptacle defines a second flow area, and wherein a cross section of the extraction tube defines a third flow area, and wherein the first flow area is greater than the second flow area, and wherein the second flow area is greater than the third flow area.
- 17. A method as in claim 16, wherein the ratio of the first flow area to the second flow area and to the third flow area is about 2.0:1.5:1.0.
- 18. A method as in claim 13, further comprising piercing a hole through the top end of the receptacle and inserting the extraction tube into the cavity through the hole in the top end.
- 19. A method as in claim 13, further comprising introducing the gas stream into the extraction tube at a location spaced apart from the bottom end of the extraction tube.
- 20. A method as in claim 13, further comprising forming a hole in the bottom end of the receptacle body, and flowing the gas stream through the hole in the bottom end.
- 21. A method as in claim 13, further comprising a patient inhaling to produce the gas stream.
- 22. A method as in claim 13, further comprising releasing an amount of pressurized gas to produce the gas stream.
 - 31. A system for aerosolizing a powdered medicament, the system comprising:

at least one receptacle that comprises a receptacle body that defines an enclosed cavity, wherein the receptacle body has a top end and a bottom end, and wherein the

bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity; and

an aerosolizing apparatus having a holder for holding the receptacle, an extraction tube that is insertable into the cavity, a vent forming device to form multiple vents in the top end of the receptacle about a periphery of the cavity.

- 32. A system as in claim 31, further comprising a pressure source for producing a high pressure gas stream within at least a portion of the extraction tube to draw air through the vents to move the powder from the cavity and into the extraction tube where the powder is entrained in the high pressure gas stream to form an aerosol.
- 33. A system as in claim 32, further comprising a flow insert to control spacing of the extraction tube relative to the receptacle.
- 34. A system as in claim 32, wherein a portion of the bottom end of the receptacle is flat in geometry.

(9) Evidence Appendix

none

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(10) Related Proceedings Appendix

none